California Environmental Protection Agency

Air Resources Board

RISK MANAGEMENT GUIDELINES

for

NEW AND MODIFIED SOURCES OF TOXIC AIR POLLUTANTS

Approval Date: July 1993

RISK MANAGEMENT GUIDELINES FOR NEW AND MODIFIED SOURCES OF TOXIC AIR POLLUTANTS

State of California
AIR RESOURCES BOARD

Resolution 93-47

July 8, 1993

Agenda Item No.: 93-8-1

WHEREAS, Health and Safety Code sections 39600 and 39605 authorize the Air Resources Board (the "Board") to act as necessary to execute the powers and duties granted to and imposed upon the Board and to assist the local air pollution control and air quality management districts (the "districts");

WHEREAS, the Board has held a duly noticed public meeting to consider approval of the Proposed Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants (the "Proposed Guidelines") and has heard and considered the written comments and public testimony from affected industries, districts, and other interested persons;

WHEREAS, the Board staff has proposed these guidelines in response to the Board's direction to work with all interested parties to develop tools and methods to assist risk managers in making risk management decisions;

WHEREAS, the Board finds that:

The Proposed Guidelines will provide risk managers with greater flexibility by allowing a number of relevant factors, identified in a Specific Findings Report, to be considered when making permitting decisions; and

The Proposed Guidelines will promote a uniform framework that will provide businesses and industries with a consistent regulatory approach to risk management decision-making statewide.

NOW, THEREFORE, BE IT RESOLVED that the Board hereby approves the Proposed Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants, as set forth in Attachment A to this resolution.

BE IT FURTHER RESOLVED that the Executive Officer is directed to forward the Proposed Guidelines to the districts for consideration when developing risk-based toxic new source review rules or policies.

BE IT FURTHER RESOLVED that the Executive Officer is directed to provide assistance to any district requesting assistance in interpreting or implementing the risk management methodology described in the Proposed Guidelines.

BE IT FURTHER RESOLVED that the Board directs the staff to continue to work with the Office of Environmental Health Hazard Assessment on issues concerning the evaluation of noncancer risk and provide additional guidance in this area as needed.

I hereby certify that the above is a true and correct copy of Resolution 93-47, as adopted by the Air Resources Board

Pat Hutchens

Pat Hutchens, Board Secretary

ATTACHMENT A

RISK MANAGEMENT GUIDELINES
FOR NEW AND MODIFIED SOURCES OF TOXIC AIR POLLUTANTS

CALIFORNIA AIR RESOURCES BOARD

NOTICE OF PUBLIC MEETING TO CONSIDER THE PROPOSED RISK MANAGEMENT GUIDELINES FOR NEW AND MODIFIED SOURCES OF TOXIC AIR POLLUTANTS.

The Air Resources Board (the "Board" or "ARB") will conduct a public meeting at the time and place noted below to consider the approval of the Proposed Risk Management Guidelines for New and Modified Sources of Toxic Air Pollutants.

DATE: July 8, 1993

TIME: 9:30 a.m.

PLACE: Air Resources Board
Board Hearing Room, Lower Level
2020 L Street
Sacramento, CA

This item will be considered at a two-day meeting of the Board, which will commence at 9:30 a.m., July 8, 1993, and will continue at 8:30 a.m., July 9, 1993. This item may not be considered until July 9, 1993. Please consult the agenda for the meeting, which will be available at least 10 days before July 8, 1993, to determine the day on which this item will be considered.

In this item, the ARB staff is proposing guidance to assist local air pollution control districts and air quality management districts (districts) in making permitting decisions for new and modified sources of toxic air pollutants. The guidelines provide suggestions for managing both cancer and noncancer health risks from these sources, and they provide background information to educate the reader on pertinent risk assessment and risk management issues. The guidelines are not intended to address all possible permitting issues, but they are intended to provide a general framework which districts may use when developing risk-based toxic new source review rules or policies. The guidelines are non-regulatory. Districts may adopt rules or policies that are different.

We are proposing these guidelines in response to our Board's direction to work with all interested parties to develop tools and methods to assist risk managers in making risk management decisions. The Board's direction came as a result of testimony presented at its October 1991 hearing to identify perchloroethylene as a toxic air contaminant. The Board heard testimony that risk management decisions are far too rigid and do not recognize that there are uncertainties inherent in the present risk assessment process. That is, permit decisions might be based strictly on risk values without providing any flexibility or consideration of other factors.

The guidelines address these concerns by proposing that districts use a combination of specific risk levels and an action range to evaluate new and modified sources of toxic air pollutants. A specific risk level is suggested for triggering the installation of the best available control technology for toxics (T-BACT) and for identifying the upper level maximum risk. An action range is suggested for providing flexibility for considering, in addition to risk, other factors such as benefits of the

project, uncertainty in the risk assessment process, legal mandates, and the impact to sensitive receptors. A discussion of these other factors would be provided in a document called a Specific Findings Report. The Air Pollution Control Officer (APCO) would review this report and prepare findings supporting a decision to approve or deny the project.

The suggested risk levels have been established based on a balanced consideration of the technological feasibility and economic reasonableness of risk reduction methods, uncertainties and variabilities in health risk assessments, protection of public health, and the districts' resources necessary to prioritize and process permits.

If approved by the Board, the proposed guidelines will provide districts with an approved methodology that they can use when considering risk in the permitting of new or modified sources.

The staff will present a written report at the meeting. Interested members of the public may also present comments orally or in writing. Written comments must be filed with the Board Secretary, Air Resources Board, P.O. Box 2815, Sacramento, California 95812, no later than 12:00 noon, Wednesday, July 7, 1993, or received by the Board Secretary at the meeting. Twenty copies of any written statement should be submitted.

Copies of the written report may be obtained from the Board's Public Information Office, 2020 L Street, Sacramento, CA 95814, (916) 322-2990, beginning Friday, June 11, 1993. Further inquiries regarding this matter should be directed to Alexander Santos, Air Resources Engineer Associate, at (916) 327-5638.

CALIFORNIA AIR RESOURCES BOARD

James D. Boyd
Executive Officer

Date: June 10, 1993

PROPOSED RISK MANAGEMENT GUIDELINES

for

New and Modified Sources
of Toxic Air Pollutants

California Environmental Protection Agency
Air Resources Board
Stationary Source Division
P.O. Box 2815
Sacramento, CA 95812

Release Date: June 1993

Primary Authors

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Reviewed and Approved by

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This draft document been reviewed by the staff of the Air Resources Board and approved for release. Approval does not signify that the contents necessarily reflect the views and policies of the Air Resources Board; nor does mention of trade names or commercial products constitute endorsement or recommendation for use.

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I. OVERVIEW

A. What is the purpose of these risk management guidelines?

This document is the Air Resources Board (ARB/Board) staff proposed guidance to assist local air pollution control districts and air quality management districts (districts) in making permitting decisions for new and modified stationary sources of toxic air pollutants. These risk management guidelines provide direction on managing potential cancer and noncancer health risks from these sources. These potential risks are quantified using a health risk assessment. The guidelines also provide background information to help educate the reader on pertinent risk assessment and risk management issues.

The guidelines are not intended to address all possible permitting issues. The guidelines do provide, from a statewide perspective, a general framework which districts may use when developing risk-based toxic new source review rules or policies. We recognize that individual districts will need to tailor these guidelines to their own specific air quality situations and needs. These guidelines should not be viewed as being minimum or maximum requirements, but rather as a framework for local decision-making.

We are focusing on guidelines for new and modified stationary sources because there are other control programs either in place or under development for existing sources. These programs include: the Toxic Air Contaminant Identification and Control Program, developed pursuant to Assembly Bill 1807; the Risk Reduction Audit and Plan Program, currently being developed pursuant to Senate Bill 1731; and the district's existing source regulatory control programs. We expect the guidelines for new and modified sources to complement the existing source control programs.

B. Why are we proposing risk management guidelines?

We are proposing risk management guidelines in response to our Board's direction to work with all interested parties to develop tools and methods to assist risk managers in making risk management decisions. The Board's direction came as a result of testimony presented at its October 1991 hearing to identify perchloroethylene as a toxic air contaminant. The Board heard testimony from many people expressing concern about how risk management decisions are made in California. Some suggested that risk management decisions are far too rigid and do not recognize that there are uncertainties inherent in the present risk assessment process. That is, permit decisions might be based strictly on a risk value, without providing any flexibility or consideration of other factors.

We have identified three main reasons why these guidelines are important. First, recognizing that uncertainty and variability are inherent in current risk assessment methodology, the guidelines suggest the use of an "action range." An action range approach provides greater flexibility by allowing other factors identified in a Specific Findings Report to be considered when making a permitting decision. Second, the guidelines provide a Board-approved methodology for districts to use when considering

risk in the permitting of new and modified sources. This provides the districts with a foundation for explaining permit decisions. Third, the guidelines promote a uniform framework within which districts can accommodate their specific needs. A uniform framework will provide businesses and industries with a consistent regulatory approach statewide and minimize duplication of federal, state, and district requirements.

C. What are we proposing?

We are proposing that districts use a combination of specific risk levels and an action range to evaluate new and modified sources of toxic air pollutants. A specific risk level is suggested for triggering the installation of toxic best available control technology (T-BACT) and as an upper level maximum risk. An action range is suggested for providing flexibility for considering, in addition to risk, other factors such as the benefits of the project, the uncertainty in the risk assessment process, the need to comply with a state or federal mandate, and the impact on sensitive receptors. A discussion of these other factors would be provided in a Specific Findings Report. The Air Pollution Control Officer (APCO) would review this report and prepare findings supporting a decision to approve or deny the project.

The suggested risk levels have been established based on a balanced consideration of the technological feasibility and economic reasonableness of risk reduction methods, uncertainties and variabilities in health risk assessments, protection of public health, and the districts' resources necessary to process and prioritize permits. A discussion of the basis for the suggested risk levels is provided in Section III. E. (page 17).

The suggested approach allows onsite risk reductions to be considered when determining the overall project impact. However, we suggest that T-BACT be installed on new or modified units increasing risk above the trigger level.

The guidelines do not provide procedures for the use of offsite risk reductions. This issue has been raised numerous times during the development of these guidelines. In theory, the idea of allowing risk reductions achieved at one source to be used when permitting another source is quite reasonable. However, in practice, an offsite risk reduction program for toxic pollutants would be resource intensive, difficult to administer, and present significant compliance problems.

For new sources of toxic air pollutants, we are proposing the following (a detailed flow chart for the process is presented on page 22):

- Districts require T-BACT on any permit unit that results in a potential cancer risk greater than or equal to 1 per million, or the total hazard index value greater than 0.2, or both.

- Districts approve a new source* if the potential cancer risk is less than 10 per million and the total hazard index value is less than or equal to 1.

- An APCO may approve a new source based on specific findings if the potential cancer risk is within the "action range" between 10 and 100 per million, or the total hazard index value is between 1 and 10, or both.

- Districts not approve a new source if the potential cancer risk is greater than or equal to 100 per million, or the total hazard index value is greater than 10, or both.

For modifications to existing sources, we are proposing the following (a detailed flow chart for the process is presented on page 26):

- Districts require T-BACT on any modified permit unit that results in an increase in the potential cancer risk greater than or equal to 1 per million, or a total hazard index value greater than 0.2, or both.

- Districts approve a modification project, without an analysis of the entire existing source (post-project) risks, if the project's maximum increase in potential cancer risk is less than 1 per million and the total hazard index is less than or equal to a value of 0.2.

  Note: This includes any project where there is a net decrease in total source risk (onsite risk reduction), provided T-BACT is used on any modified permit unit subject to T-BACT requirements.

- Districts approve a modification project if the entire existing source (post-project) potential cancer risk is less than 10 per million and a total hazard index value is less than or equal to 1.

- An APCO may approve a modification project, based on specific findings, if the entire existing source (post-project) potential cancer risk is within the "action range" between 10 and 100 per million, or the total hazard index value is between 1 and 10, or both.

- Districts not approve a modification project if the project's maximum increase in potential cancer risk is greater than or equal to 100 per million, or is greater than a total hazard index value of 10, or both.

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For the purpose of these guidelines a source is all permit units or activities at one location (see definition on page 15).

- Districts not approve a modification project if the project's maximum increase in potential cancer risk is greater than or equal to 1 per million or a total hazard index value greater than 0.2, and the entire existing source (post-project) potential cancer risk is greater than or equal to 100 per million, or is greater than a total hazard index value of 10, or both.

D. What are the significant risk assessment issues and how are we proposing to address them?

There are two major issues associated with the use of risk assessments in making risk management decisions. The first issue is related to the inherent uncertainty associated with the development of risk values used in risk assessments. For example, uncertainty results from the extrapolation of toxicity data in animals to estimate cancer potency in humans. One approach that can be taken to address uncertainties in the development of risk values is to consider the use of weight-of-the-evidence. Weight-of-the-evidence considers how much data are available that demonstrate an adverse health effect in humans and the quality of that data.

The second issue is related to the methodology used in risk assessments for determining exposures. Some argue that the use of a more comprehensive and detailed methodology would provide the risk manager with more accurate information upon which to base a decision. The methodology would incorporate factors such as emissions variability, air dispersion model uncertainty, population mobility and mortality, human activity patterns, physical exercise levels, and differences between indoor and outdoor exposures.

In these guidelines, we are not proposing to revise the methodology for preparing risk assessments. The Office of Environmental Health Hazard Assessment (OEHHA), within the California Environmental Protection Agency (Cal/EPA), is the state agency with the primary responsibility for providing the ARB and districts with scientific information and advice on the health effects of chemicals in the air. The OEHHA is currently leading the process of re-evaluating its cancer guidelines and re-assessing the exposure models.

In this process, the OEHHA will consider the results and findings of a number of completed and ongoing studies. These studies discuss uncertainties and alternative approaches and are described in Appendix 1. Also, input will be sought from interested members of the public through public workshops and work-group meetings. We anticipate that in 1994 the OEHHA will complete revisions to their cancer guidelines entitled Guidelines for Chemical Carcinogen Risk Assessment and Their Scientific Rationale.

In addition, Senate Bill (SB) 1731 (Risk Reduction Audits and Plans) requires that the OEHHA develop and adopt health risk assessment guidelines. These guidelines will allow sources to include "supplemental information" such as probability distributions, microenvironmental characteristics, population distributions, and descriptions of incremental reductions of risk when exposure is reduced. Input will be sought from interested members of

the public through public workshops and work-group meetings. The Scientific Review Panel on Toxic Air Contaminants (SRP) will also review and provide its comments on the OEHHA guidelines.

While we are not proposing to revise the current OEHHA-recommended risk assessment methodology, we do believe the action range approach presented in these guidelines provides risk managers with greater flexibility in recognition of the uncertainties in the current risk assessment process. Currently, if a project's potential cancer risk exceeds a specific risk level (generally 10 per million) the permit is denied. Under the proposed approach, if the project's potential cancer risk is within the action range, (suggested risk level 10 to 100 per million), factors identified in a Specific Findings Report can be taken into consideration when making a risk management decision.

It is important to note that these guidelines are based on current risk assessment guidelines. Therefore, if the OEHHA revises the risk assessment methodology, we believe that it is appropriate to reevaluate these guidelines including the suggested risk levels.

E. How were these guidelines developed?

These guidelines were developed through a series of workshops and meetings with representatives from the districts, environmental groups, trade associations, industry, and governmental agencies. In March and April 1992, we conducted three scoping workshops to solicit ideas concerning the needs of risk managers, the use of risk values in risk management, and the improvement of risk management decision making. In May 1992, we held a series of meetings with districts, industry, environmental groups, and other state agencies to identify possible approaches for the guidelines. In September, we conducted a workshop to discuss a concept paper on possible approaches. At this workshop, we received numerous comments concerning the need to have specific risk values to streamline permitting. We also heard comments supporting more flexibility in the permitting process to allow for consideration of other factors in addition to the risk level. As a result of these comments, we selected the "action range" approach for development.

In January 1993, we met with district and industry representatives to discuss the "action range" approach. In late March, we released the draft risk management guidelines. We again held a series of meetings with districts, industry, environmental groups and other state agencies to receive comments on the guidelines. We held a public workshop on April 20, 1993, in San Francisco to discuss the draft guidelines. We have developed these proposed guidelines based on the input received at these workshops and meetings.

An important factor in the development of these guidelines was to consider the relationship among these guidelines and other air toxics programs such as those required by Assembly Bill (AB) 2588 (Air Toxics "Hot Spots" Information and Assessment Act of 1987), AB 1807 (Toxic Air Contaminant Identification and Control), SB 1731 (Risk Reduction Audits and Plans) and the requirements of the Federal Clean Air Act (FCAA).

(See Appendix 2 for descriptions of these programs.) To the maximum extent possible, these guidelines are consistent with, and complement, the requirements of the other programs.

In developing permitting programs based on these guidelines, we acknowledge that the districts need to consider the relationship between the significant risk level and the unreasonable risk level identified as part of SB 1731 (Risk Reduction Audits and Plans) and the risk levels selected for toxic new source review.

We further acknowledge that issues still remain concerning whether these guidelines are wholly consistent with the programs being developed by the United States Environmental Protection Agency (U.S.EPA) to address FCAA requirements. U.S.EPA is still in the process of developing control technology standards, emissions averaging provisions, de minimis levels, and program equivalency determinations. Because these provisions are not yet promulgated, we can not be sure that the U.S.EPA's approach and our approach will be wholly consistent. However, we believe that the approach proposed will be at least as effective as the U.S.EPA approach with respect to control technology standards. We will work with U.S.EPA and the districts to ensure a smooth integration of FCAA requirements into districts' toxic programs.

F. Must districts implement these guidelines?

No. The districts are not legally required to implement these guidelines. These guidelines are not regulatory, hence not binding on the districts. However, they offer the districts a Board-approved methodology and framework to assist them in applying risk assessment information in risk management decisions. These guidelines are not intended to preclude the districts from developing toxic new source review programs with requirements that are different from those suggested in the guidelines.

We have worked closely with the districts in developing these guidelines. This effort has provided a valuable forum for discussing risk management issues and resulted in a better understanding of the strengths and weaknesses of risk-based regulations. Therefore, we are optimistic that the final guidelines will be useful to the districts in developing and implementing new source review programs for sources of toxic air pollutants.

We acknowledge that the South Coast and the Bay Area Air Quality Management Districts are currently developing toxic new source review rules that differ in some aspects from these guidelines. However, we believe their general framework will be consistent with what we are proposing. Also, several other districts have expressed interest in developing toxic new source review rules in the near future.

II. BACKGROUND

The purpose of this section is to provide background information on regulatory methodology which considers risk. In this section, we define the terms risk assessment and risk management and discuss how risk assessment and risk management are used in California to regulate toxic air emissions. Our focus is primarily on new and modified sources of toxic air emissions; however, we do discuss current programs for existing sources where appropriate.

Currently, the analysis of risk is a widely used approach for characterizing and regulating toxic emissions in air, water, and solid waste. Some European countries have or are considering schemes of risk-based regulation. Britain, the Netherlands, and Norway are European countries in which risk-based regulation of acutely hazardous materials are most developed.* The U.S.EPA, the Nuclear Regulatory Commission, and the Department of Energy are three examples of federal agencies that use quantitative estimates of risk as a tool when making regulatory decisions.

In California, many agencies use risk assessments in carrying out their programs. These agencies include the ARB, the Department of Pesticide Regulation, the Department of Toxic Substances Control, the Water Resources Control Board, and the OEHHA. At the local level, the South Coast Air Quality Management District, the Bay Area Air Quality Management District, the Monterey Bay Unified Air Pollution Control District and many of the other districts have toxic new source review policies or rules which incorporate risk-based criteria in their decision-making processes.

A. What is a health risk assessment?

Risk assessment is an evaluation of the potential adverse health effects from exposure to environmental hazards. Risk assessments are used both to determine the potential for a particular substance to cause adverse health effects and to determine the potential for a particular source to impact public health. In general, the risk assessment process may be divided into four major steps: hazard identification, dose-response, exposure assessment, and risk characterization.

Hazard identification involves determining whether exposure to a particular substance will result in some type of harm. It attempts to determine whether a hazard exists, and if so, what it is. Once the hazard has been identified, the dose-response assessment is used to determine what level exposure results in adverse effects. In the exposure assessment step, it is determined who is likely to be exposed. Exposure may be by skin

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Ultramar Inc., November 1991, An Approach to Risk Based Regulation, A Discussion Paper.

contact, ingestion, or inhalation. The magnitude of the exposure (e.g. how long, how often, and what concentration) is also determined.

Risk characterization is the final step in the risk assessment process. This step integrates information from the other parts of the risk assessment to estimate risks associated with individual substances, sources or activities. The risk estimates generally include cancer risk and noncancer health risk. Appendix 3 provides further details concerning risk assessment.

When determining the potential for a particular substance to cause adverse health effects such as cancer, the OEHHA's cancer risk guidelines entitled Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale are used. Scientists evaluate the health effects data, examine the biological characteristics of the substance, and estimate the probable incidence of cancer and adverse health effect to humans at a given exposure level. The quantitative assessment of cancer risk is evaluated based on a cancer potency value. Cancer potencies and unit risks describe the probability or risk of cancer from a given dose or exposure level. Cancer potencies are based on dose per day (e.g., per mg/kg-day) and unit risks are based on annual exposure (per ug/m^3). In addition, acceptable exposure levels for the particular compound are developed for acute and chronic noncancer health effects evaluation.

When determining the potential for a particular source to impact public health, the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines (January 1992) are used. The source health risk assessment utilizes emissions data and health effects information developed for the particular substance(s) emitted from the source. This information is used to determine potential exposure concentrations via various exposure pathways. Once the potential exposure is determined and combined with the health effects information, the potential cancer and noncancer health risk for an individual can be calculated generally assuming 70 years of continuous exposure.

The maximum excess cancer risk and the cancer burden are two ways cancer risk can be expressed. The maximum excess cancer risk is an estimate of the highest cancer risk at any offsite location. A potential maximum excess cancer risk location is not only limited to locations where receptors currently exist (e.g, residences, businesses), but also includes locations zoned for future development and unoccupied areas. Cancer burden is an estimate of the potential increased number of cancer cases in a population as a result of exposure to emitted substances.

Noncancer acute and chronic effects are also analyzed and usually expressed as a fraction of the acceptable exposure level called the hazard index value. The hazard index value for a given ambient concentration of a toxic air pollutant is the ratio of the concentration of the toxic air pollutant in the ambient air to the applicable acceptable exposure level for that toxic. A hazard index value is determined for each target organ or

organ system. Hazard index values from different toxic air pollutants that affect the same target organ or organ system are summed to calculate a total hazard index.

Risk assessments have several sources of uncertainty which are discussed in the next section. Risk estimates generated by a risk assessment should not be construed as the expected rates of disease in the exposed population but merely estimates of potential risk, based on current knowledge and specified assumptions.

B. What are the sources of uncertainty in risk assessment?

There is uncertainty associated with the process of risk assessment. This uncertainty arises from both the scientific process of risk assessment and the available data. For example, a major area of uncertainty is the extrapolation of the toxicity data in animals to estimate cancer potency in humans.

The estimates of cancer potency in humans are affected by factors such as metabolism, target site sensitivity, diet, immunological responses, and genetics. Variability in these factors, within animal species and within the human population, usually cannot be easily quantified and incorporated into risk assessments. The human population is much more diverse both genetically and culturally (e.g. lifestyle, diet) than are experimental animals. The intraspecies variability among humans is expected to be much greater than in laboratory animals.

Another source of uncertainty in estimating cancer potency involves the assumptions underlying the dose-response model used. A dose-response model is used to extrapolate the large experimental doses given to animals over their lifetime to the much smaller environmental doses a human might receive over a 70-year lifetime. Less uncertainty is involved in the extrapolations from workplace exposures to environmental exposures when epidemiological data are used to establish a dose-response relationship. However, epidemiological data are not always available.

Another area of uncertainty is in estimating the ambient concentration of a toxic pollutant. Sources of uncertainties include the accuracy of the dispersion model, the quality of the meteorological data, and the accuracy of the emission estimates.

A third area of uncertainty is in the calculation of exposure. Sources of uncertainty include the assumption of a continuous 70-year exposure period and the use of average values for parameters such as body weight and inhalation rate.

While most of the uncertainties mentioned above tend to overestimate risk, several other factors tend to underestimate risk. For example, the effects of exposure to more than one substance is not quantified in a risk assessment. Many examples of additivity or synergism (effects greater than additive) are known. For substances that act synergistically, the risk

assessment underestimates risks. Some substances can damage genetic material. The genotoxicity of substances is not currently quantified in a risk assessment.

The estimates of incidence of noncancer adverse health effects are also affected by similar uncertainties. The derived acceptable exposure level usually includes factors of either 10, 100 or more to provide further conservatism.

C. What is risk management?

Risk management is the process of using information generated from a source health risk assessment to assist in deciding if a source should be built, modified, or allowed to continue to operate at its current level of emissions. It is important to realize that risk management is not a purely scientific process. It requires the risk manager to integrate the results of the risk assessment with other information to reach a decision. This other information includes the technical feasibility of reducing emissions and social, economic, and political concerns. The risk manager may have to make value judgements in deciding whether a risk is acceptable or not. In those cases, the risk manager must decide whether the benefit of reduced risk outweighs the time, money, and effort that would be spent to reduce it.

Some view this discretionary element of risk management as a deficiency in the risk management process, allowing for inconsistent decision-making. Others feel discretionary decision-making is necessary to allow flexibility. Most agree that any viable risk management program should provide for both discretionary and nondiscretionary decision-making. Nondiscretionary decision-making could be accommodated through the use of risk-based brightlines. Discretionary decision-making could be reserved for those sources that fall within an "action range."

D. How is risk assessment and risk management handled in California?

In the previous section, we have discussed general issues associated with risk assessment and risk management. In this section, we will present an overview of existing district, state and federal risk assessment and risk management programs. A more detailed discussion of these programs is presented in Appendix 2.

Substance Health Risk Assessment

In California, the OEHHA provides the ARB and districts with scientific information and advice on the health effects of chemicals in the air. The OEHHA analyzes particular substances for adverse health effects and determines whether the substances have potential cancer or noncancer effects. For substances with potential carcinogenic effects, the OEHHA provides potency factors that can be used in estimating excess cancer risk. The OEHHA also provides noncancer risk information to the districts and the state for use in estimating health risks from sources.

State Risk Assessment and Risk Management Activities

AB 1807 (Identification and Control) [Tanner, Chapter 1047, Stats. of 1983, Health and Safety Code sections 39650 - 39675] establishes the process for identifying and controlling toxic air pollutants. Once a toxic air pollutant is identified, the ARB adopts appropriate control measures. Following the adoption of a control measure, the districts must adopt equal or more stringent regulations. In this process, the state utilizes a technology-based risk management approach which considers risk assessment as one factor in determining the level of control for sources. Risk assessment is also used to prioritize sources for regulation development.

AB 2588 (Air Toxics "Hot Spots" Information and Assessment Act of 1987) [Connelly, Chapter 1252, Stats. of 1987, Health and Safety Code sections 44300 - 44394] requires stationary sources to report the type and quantity of certain toxic air pollutants their sources routinely release into the air. The goals of the Hot Spots Program are to collect emissions data, identify sources having localized impacts, ascertain potential health risks, and notify nearby residents of significant potential health risks.

In 1992, SB 1731 (Risk Reduction Audits and Plans) [Calderon, Chapter 1162, Stats. of 1992, Health and Safety Code sections 44390 - 44394] was signed into law. This bill amends AB 2588 (Air Toxics "Hot Spots" Information and Assessment Act of 1987) by adding two new major elements. First, the OEHHA must prepare and adopt revised risk assessment guidelines. Second, sources that pose a significant risk must prepare and implement risk reduction audits and plans. The ARB shall provide assistance to small businesses for developing and applying risk reduction techniques. The risk assessment guidelines will address issues concerning supplemental information such as probability distributions, microenvironmental characteristics, population distributions, and descriptions of incremental reductions of risk when exposure is reduced.

In 1992, AB 2728 (Coordination with the Federal Act) [Tanner, Chapter 1161, Stats. of 1992, Health and Safety Code sections 39656 - 39659] was also signed into law. This bill requires the ARB to adopt the federal hazardous air pollutants listed in section 112(b) of the Federal Clean Air Act (FCAA, 42 USC section 7400 et seq.) as toxic air contaminants. In addition, the bill specifies that any promulgated federal emission standard will become a statewide control measure, unless the ARB takes specific action to modify the federal emission standard.

District Risk Management Activities

Currently, two districts are basing permit decisions on a rule while approximately 15 districts are basing such decisions on a policy. A rule is a set of criteria that has been formally adopted. A policy is a set of guiding principles that has not been codified into a rule. Many of the districts are using an approach that incorporates

brightline trigger levels. This approach provides a consistent method for a district to regulate the emissions of toxic air pollutants from new and modified sources which must obtain a permit to construct or operate.

In general, district new or modified source permitting rules and policies establish two risk levels or brightlines. The lower risk level establishes the trigger level for T-BACT and the higher risk level establishes the trigger level for permit denial. Some districts establish a de minimis risk level below which further controls are not required. Generally, the districts have established risk levels for permit denial in the range of 1 per million to 10 per million. Some rules also establish a potential cancer burden level; for example, a source may not be permitted if more than a certain number of potential cancers are predicted based on the source's emissions.

Federal Risk Management Activities

The FCAA is another risk management program that must be followed in California. Currently, sources in California must comply with National Emission Standards for Hazardous Air Pollutants (NESHAPS). A frequently cited decision is the U.S.EPA benzene NESHAP decision in 1988. In this decision, the U.S.EPA recommended against further regulations of specific categories of existing sources with potential cancer risk below 100 per million. Our review of this decision found that U.S.EPA generally supported a risk level of 100 per million or less. We also found that U.S.EPA was very careful in characterizing this particular decision stating that the decision "...should be viewed in the narrow context of Section 112." The U.S.EPA also stated that the "...NESHAP 'acceptable risk' findings have little value in making risk judgements under other statutes, or even under other provisions of the Clean Air Act."

Recently, the FCAA was amended in an effort to achieve greater reductions in toxic air emissions. The amendments include provisions to identify priority pollutants, identify source categories for control, develop maximum available control technology (MACT) standards, address modifications, define offsets, implement and enforce the FCAA, and define permitting requirements. The U.S.EPA is also required to address, in the future, residual risk from facilities complying with MACT standards. The FCAA identified a cancer risk of 1 per million as a threshold for promulgation of residual risk standards. We acknowledge that U.S.EPA evaluation of residual risk is eight years away and the risk methodology which U.S.EPA uses may be different than what is used in California. However, the fact remains that the FCAA contemplates action whenever the risk is greater than 1 per million. Sources in California will have to comply with U.S.EPA's MACT standards or standards which are at least as stringent.

In general, the state, district, and federal programs are complementary. Rather than establishing a risk trigger level, the state's AB 1807 program first requires best available control technology. Risk and cost are weighed before making the final determination on the required level

of control. This process is lengthy but provides uniformity across a source category. For permitting, the districts need a simple and consistent approach to make numerous permitting decisions in a relatively short period of time. However, the approach should also take into consideration the inherent uncertainties in risk assessments. Federal requirements are technology-based with risk-based residual risk analysis eight years later. These guidelines, we believe, should help to provide a consistent yet flexible approach among state, district, and federal programs.

III. GUIDELINES FOR NEW AND MODIFIED SOURCES

This section defines the staff's suggested approach for evaluating new and modified sources of toxic air pollutants. In this section, we define the approach, discuss possible exemptions, define key terms, discuss the applicability of the approach, suggest source health risk assessment requirements, discuss the scope of the specific findings report, and define and discuss the suggested cancer and noncancer risk levels. The suggested approach frequently presents only one method for handling each element of the proposal. For example, for new sources we suggest T-BACT on any permit unit that has a potential cancer risk greater than or equal to 1 per million. An alternative approach might be to require T-BACT on all permit units if the project exceeds 1 per million. A third approach might be to require T-BACT on any permit unit increasing risk. We acknowledge that alternative approaches may be viable for a particular district.

A. Applicability

These guidelines are intended to apply to any new or modified stationary source that is required to obtain a permit pursuant to district regulations. These guidelines are designed to address source risks which have been evaluated in accordance with the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, (January 1992).

When evaluating cancer risk, the specific toxic air pollutants addressed by these guidelines are those that have potency values that have been developed by either the OEHHA or the U.S.EPA (see Table III-6 of the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, January 1992.)

When evaluating noncancer risk, the specific toxic air pollutants addressed by these guidelines are those that have applicable noninhalation, chronic, or acute exposure levels as identified by the OEHHA or the U.S.EPA (see Tables III-5, III-8, and III-9 of the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, January 1992).

B. Exemptions

Districts may wish to provide exemptions from these guidelines to certain categories of small businesses (e.g. drycleaners, wood furniture refinishers, gasoline service stations) which have implemented all technically feasible and cost effective control measures. We recognize that such exemptions create a certain inequity because receptors of a given risk are affected the same regardless of the size of the sources. However, we believe that districts should specifically consider the implications of their permitting rules or policies on small businesses.

C. Key terms

Permit Unit

A permit unit is any article, machine, piece of equipment, or other contrivance, or combination thereof which may cause or control the release of toxic air pollutants and which requires a written permit.

Project

A project is any permit unit or grouping of permit units or other activities which emit toxic air pollutants, located on one or more contiguous properties within a district, including properties that are separated solely by a public roadway or other public right-of-way, and which are owned or operated by the same person (or by persons under common control).

Stationary Source or Source

For the purposes of these guidelines, a stationary source or source refers to all permit units or activities which emit toxic air pollutants, located on one or more contiguous properties within a district, including properties that are separated solely by a public roadway or other public right-of-way, and which are owned or operated by the same person (or by persons under common control).

Modification

A modification is either:

(1) any physical change in, change in method of operation of, or addition to an existing permit unit that requires an application for a permit to construct and/or operate. Routine maintenance and/or repair shall not be considered a physical change. A change in the method of operation of equipment, unless previously limited by an enforceable permit condition, shall not include:

   a) an increase in the production rate, unless such increases will cause the maximum design capacity of the equipment to be exceeded; or

   b) an increase in the hours of operation; or

   c) a change in ownership of a source; or

(2) the addition of any new permit unit at an existing source.

Maximum Excess Cancer Risk (MECR)

The maximum excess cancer risk (MECR) is an estimate of the highest increased cancer risk resulting from a project's or source's emissions. The MECR is either the maximum offsite cancer risk or the maximum individual offsite cancer risk at an existing receptor, whichever is higher. See CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, (January 1992).

Toxic Best Available Control Technology (T-BACT)

T-BACT means the most effective emissions limitation or control technique which:

(1) has been achieved in practice for such permit unit category or class of source; or

(2) is any other emissions limitation or control technique, including process and equipment changes of basic and control equipment, found by the Executive Officer or Air Pollution Control Officer to be technologically feasible for such class or category of sources, or for a specific source.

Although the definition of T-BACT does not explicitly state that cost is considered when determining T-BACT, in practice we recognize that T-BACT decisions implicitly take cost into consideration.

D. Health Risk Assessment

The evaluation of potential risk from a new or modified source begins with an initial risk analysis, or in the case of a significant risk source, a health risk assessment of either the new source or the portion of the source being modified. Until the OEHHA completes its work on risk assessment guidelines, we believe that source health risk assessments should be done in accordance with the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, (January 1992). Both cancer and noncancer risk should be assessed. Cancer risk would be expressed in terms of maximum excess cancer risk (MECR), while noncancer risk would be expressed as total hazard index values. Both the chronic and the acute noncancer total hazard index values for each substance emitted should be evaluated. The total hazard index value for each endpoint organ or organ system should be determined.

The districts may want to develop specific exemptions from the requirements to prepare a health risk assessment for permit units or sources which pose an insignificant risk, or for small businesses where all feasible and cost-effective measures have been implemented. For determining that a permit unit or source poses an insignificant risk, we suggest that the districts consider the use of an alternative screening level indicator, such as a prioritization score, if the district is satisfied that the prioritization score indicates that the risk associated with the permit unit or source is not significant. Other information, such as the results of

past health risk assessments on similar permit units or sources, may also be useful in establishing alternative screening level indicators.

If a health risk assessment is required, the districts may want to consider allowing the use of a screening level health risk assessment. If the screening level health risk assessment indicates that any applicable risk level is exceeded, the applicant should be given the option of performing and submitting a detailed health risk assessment.

There are two relatively inexpensive models that can be used to conduct screening risk assessments. The first is the Health Risk Assessment (HRA) program developed by the ARB and OEHHA. The second is the Assessment of Chemical Exposure for AB 2588 (ACE2588) program developed by the Santa Barbara County Air Pollution Control District with Applied Modeling, Incorporated. Information on the HRA model can be obtained by contacting the Air Resources Board at (916) 327-5635. Information on the ACE2588 model can be obtained by contacting the California Air Pollution Control Officers Association at (916) 676-4323.

The districts are encouraged to incorporate into their risk management programs the streamlining concepts contained in the AB 2588 (Air Toxics "Hot Spots" Information and Assessment Act of 1987) emission inventory reporting requirements. For example, when evaluating an entire modified source's risk, it may be appropriate to require health risk assessment information on only the substantial risk devices.

E. Risk Levels

To accommodate the districts' need to process permits in a timely and consistent manner, we integrated suggested risk levels into this risk management approach. The use of these risk levels is discussed in subsections F and G. All of these risk levels are based on current risk assessment methodologies and are generally consistent with current risk management practices. We believe these risk levels recognize the uncertainty in risk assessments, are achievable with currently available risk reduction methods, and provide public health protection. We believe that these levels are appropriate in the context of the current risk assessment methodology. If OEHHA significantly revises its guidance on performing health risk assessments, we believe it would be appropriate to reevaluate the proposed risk levels. The rationale for the selection of these levels is presented in the following paragraphs.

Cancer risk levels

We suggest that the districts consider the potential cancer risk levels specified in Table 1.

TABLE 1: Potential Cancer Risk Levels
(Maximum Excess Cancer Risk)

T-BACT Trigger Level	1 per million
ACTION RANGE	
Lower Level	10 per million
Upper Level	100 per million

We suggest 1 per million as the cancer risk level which triggers T-BACT for new and modified sources. We believe that new or modified permit units should install T-BACT during the initial permitting action rather than attempting to retrofit controls at a later date. However, we recognize that limited district resources and permit workload generally preclude such an analysis for all new or modified permit units. Setting a T-BACT trigger level allows districts to make non-discretionary decisions, thereby simplifying the permit process. We believe that a T-BACT trigger level of 1 per million provides a balance between the desire to implement T-BACT on all new or modified permit units and the need to process permits in a timely manner. This approach is analogous to the approach used for BACT under criteria pollutant new source review rules.*

We suggest 10 per million as the upper level cancer risk for non-discretionary permitting decisions and as the lower level cancer risk for discretionary permitting decisions within the action range. Several large districts in California use 10 per million cancer risk as an achievable risk management goal. Several states use one per million or ten per million as a trigger either for T-BACT or for discretionary permitting decisions. We believe this risk value to be a reasonable benchmark balancing technical and economic feasibility, uncertainty in risk assessment methods, and public health protection.

A value of 100 per million is suggested as the upper level cancer risk for permitting decisions, either discretionary or non-discretionary for new and modified sources. This choice represents an order of magnitude increase from the lower risk level. We believe that it is highly unlikely that a new or modified source with a potential cancer risk

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* Districts may wish to allow some permit units with risk greater than 1 per million to be permitted without T-BACT provided that: 1) the post-project entire source cancer and noncancer risk levels are less than or equal to the levels that would have been achieved if T-BACT had been installed, and 2) the post-project entire source risk is less than 10 per million and the total hazard index is less than or equal to 1 or both.

above 100 per million will be built in California. Ninety (90) percent of the AB 2588 health risk assessments which the OEHHA has reviewed to date reported risks of less than 100 per million. These assessments are for existing sources, and we expect new facilities to have significantly lower risks. By suggesting a cap of 100 per million, we also provide the public with some assurance that emission increases will not occur at existing facilities currently over 100 per million. We believe an upper risk level of 100 per million is appropriate at this time, given current risk assessment methodology and the approach proposed in these guidelines.

Noncancer risk levels

We suggest that the districts consider the noncancer risk levels specified in Table 2.

TABLE 2: Noncancer Risk Levels
(Total Hazard Index)

T-BACT Trigger Level	0.2
ACTION RANGE	
Lower Level	1
Upper Level	10

The potential noncancer adverse health effects of both short-term (acute) and long-term (chronic) exposure are an important part of any permit evaluation for toxic pollutants. Such an evaluation involves comparing the estimated concentration of a substance with an acceptable exposure level for that substance. Acceptable exposure levels are used as indicators of potential adverse health effects. They are generally based on the most sensitive adverse health effect reported in the literature.

For a single substance, exposure at or below the acceptable exposure level is not expected to result in adverse health effects. Exposure above the acceptable exposure level does not necessarily equate to a significant health risk, but they warrant further examination.

The estimate of noncancer health effects is generally expressed as the ratio of the estimated ambient concentration of a substance to the acceptable exposure level. This ratio is referred to as the hazard index. In the case of exposure to multiple substances with noncancer health effects, it is necessary to calculate a total hazard index. A total hazard index is determined by calculating the hazard index by target organ for each substance and summing these values for each target organ (see CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, January 1992).

We suggest a noncancer total hazard index value of 0.2 as the T-BACT trigger for new and modified sources. We believe that all new or modified permit units should be installed with T-BACT during the initial permitting action rather than attempting to retrofit controls at a later date. However, we recognize that limited district resources and permit workload generally preclude such an analysis for all new or modified permit units. Setting a T-BACT trigger level allows districts to make non-discretionary decisions, thereby simplifying the permit process. We selected 0.2 because this value was being achieved by over 60 percent of existing sources with health risk assessments that the OEHHA had reviewed as of May 1993. Since new sources and modifications should be able to achieve better control than existing sources, we believe 0.2 was a reasonable value. The selection of 0.2 is also consistent with recommendations of the SCAQMD in their proposed amendments to their toxic new source review rule (Rule 1401). We believe that a T-BACT trigger level of 0.2 provides a balance between the desire to implement T-BACT on all new or modified permit units and the need to process permits in a timely manner.

We suggest a total hazard index value of 1 as the upper level noncancer risk for non-discretionary permitting decisions and as the lower level noncancer risk for discretionary permitting decisions within the action range. The OEHHA believes that a total hazard index value at or below 1 does not indicate an adverse noncancer risk. Conversely, the OEHHA believes that a total hazard index value above 1 indicates that the source has a significant potential to cause adverse noncancer risks.

We suggest a total hazard index value of 10 as the upper level noncancer risk for permitting decisions, either discretionary or non-discretionary for new and modified sources. This choice represents an order of magnitude increase from the lower risk level. We believe that it is unlikely that a new or modified source with a total hazard index greater than 10 will be built in California. We currently do not have complete information on the noncancer risk associated with AB 2588 (Air Toxics "Hot Spots" Information and Assessment Act of 1987) risk assessments that OEHHA has received. We do, however, have noncancer risk information from 46 existing sources. The risk assessments for these sources have been approved by the Santa Barbara County Air Pollution Control District. This data indicates that all 46 sources have a total chronic hazard index of 10 or less. Eighty-five percent of the sources have a total acute hazard index of 10 or less.

We have received comments that the proposed noncancer hazard index value may not be appropriate for some compounds (i.e. beryllium, hydrogen sulfide, and nickel) emitted by certain sources. We believe it appropriate for districts to consider these situations on a case-by-case basis.

F. Approach for New Sources

The suggested approach for evaluating new sources requires the permit unit to be analyzed for T-BACT requirements and the overall source risk to be evaluated. The decision to issue or deny a permit is based on an

evaluation of both cancer and noncancer risk. For example, if the noncancer risk evaluation requires the permit to be denied, the permit would be denied regardless of the outcome of the cancer risk evaluation. In determining the potential risk for a new source, we suggest that the districts use the maximum permitted emissions.

The following text and Figure 1 describe the suggested approach for evaluating new sources of toxic air pollutants. An example is also provided to illustrate how the approach is to be used.

STEP 1: EVALUATION OF POTENTIAL CANCER RISK - NEW SOURCES

A. Permit Unit T-BACT Analysis (Figure 1)

T-BACT would be required on each permit unit whose maximum permitted emissions result in a potential MECR greater than or equal to 1 per million.

B. New Source Risk Evaluation (Figure 1)

New source's MECR less than 10 per million

A new source with a potential MECR estimate less than 10 per million, after permit unit T-BACT requirements are met, would be approvable.*

New source's MECR greater than or equal to 10 per million and less than 100 per million

A new source with a potential MECR estimate greater than or equal to 10 per million and less than 100 per million, after permit unit T-BACT requirements are met, is approvable provided the applicant submits a Specific Findings Report and the APCO finds that a permit should be issued.

A Specific Findings Report should be prepared by the permit applicant. The report should present information that the APCO requires and information the applicant believes the APCO should consider in making the decision on the project. A discussion of what might be provided in a Specific Findings Report is provided in subsection J. We believe that it is important for the APCO to prepare a report providing the basis for approving or denying the permit.

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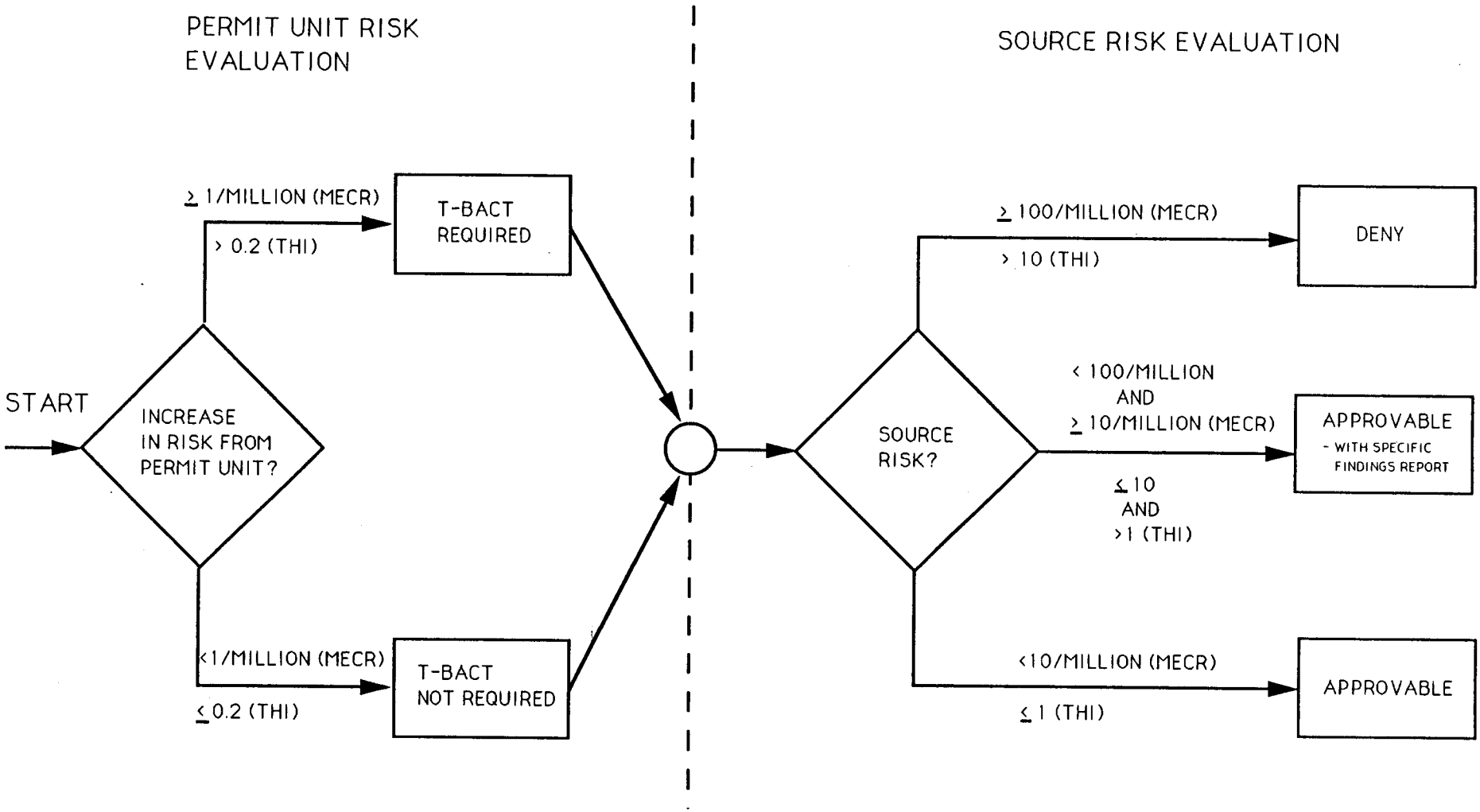
* Assuming source meets the potential noncancer risk requirements, all other district requirements, any applicable state toxic control measures, and any federal MACT requirements.

Figure 1: Overview of the New Source Cancer and Noncancer Risk Evaluation Process



NOTE: CANCER RISK AND NONCANCER RISK ARE EVALUATED SEPARATELY.

MECR = MAXIMUM EXCESS CANCER RISK

THI = TOTAL HAZARD INDEX

New source's MECR greater than or equal to 100 per million

A new source with a potential MECR estimate greater than or equal to 100 per million, after permit unit T-BACT requirements are met, would be denied a permit.

STEP 2: EVALUATION OF NONCANCER RISK - NEW SOURCE

A. Permit Unit T-BACT Analysis (Figure 1)

T-BACT would be required on each permit unit whose maximum permitted emissions result in a potential MECR greater than 0.2.

B. Entire New Source Risk Evaluation (Figure 1)

New source's total hazard index value is less than or equal to 1

A new source with a total hazard index value less than or equal to 1, after permit unit T-BACT requirements are met, would be approvable.*

New source's total hazard index value is greater than 1 but less than or equal to 10

A new source with a total hazard index value greater than 1 but less than or equal to 10, after permit unit T-BACT requirements are met, is approvable provided the applicant submits a Specific Findings Report and the APCO finds that a permit should be issued.

New source's total hazard index value is greater than 10

New sources with a total hazard index value greater than 10, after permit unit T-BACT requirements are met, would be denied a permit.

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* Assuming source meets the potential cancer risk requirements, all other district requirements, any applicable state toxic control measures, and any federal MACT requirements.

EXAMPLE CASE

A new source consists of permit units A, B, and C.

Risk information:

Permit Unit	Cancer Risk	Noncancer Risk
A	5 per million	1
B	0.5 per million	0
C	30 per million	5

Evaluation:

Permit Unit T-BACT Analysis: T-BACT for cancer risk is required on permit units A and C. T-BACT for noncancer risk is required on permit units A and C.

Risk information after Permit Unit T-BACT installed:

Permit Unit	Cancer Risk	Noncancer Risk
A	0.5 per million	0
B	0.5 per million	0
C	2 per million	3

Entire New Source Risk Evaluation: The new source potential cancer risk is 3 per million; the noncancer total hazard index value is 3. The new source is approvable provided the applicant submits a Specific Findings Report for noncancer risk and the APCO concludes the permit should be approved.

G. Approach for Modified Sources

The suggested approach for evaluating modified sources requires an analysis of each new or modified permit unit to determine if T-BACT is required, an evaluation of the overall project risk, and, depending on the result of the project evaluation, an evaluation of the entire-source risk. As with new sources, a separate evaluation of both cancer and noncancer risk is suggested. The following text and Figure 2 describe the suggested approach for evaluating modified sources of toxic air pollutants. An example illustrating the approach is also provided.

An issue that has been raised concerns the appropriateness of requiring a total health risk assessment for sources, such as oil production facilities, which cover large areas. In these cases, a total facility health risk assessment could be extremely expensive. We have not addressed this in the proposed guidelines. We believe it may be appropriate for districts to modify the proposed approach to address this particular issue.

STEP 1: EVALUATION OF POTENTIAL CANCER RISK - MODIFIED SOURCE

A. Permit Unit T-BACT Analysis (Figure 2)

T-BACT would be required on each modified permit unit whose emissions result in an increase in potential MECR greater than or equal to 1 per million.

Note: We suggest that the districts use the maximum permitted emissions to determine the difference between the post-project risk and pre-project risk from each modified permit unit. The use of actual emissions to determine the pre-project risk may be more appropriate in situations where the pre-project emissions have not been established by enforceable permit conditions and where the permitted emissions have not been used to assess risk in a previous district permitting action. In this case, we suggest that the districts use the actual average annual emissions.

B. Project Risk Evaluation (Figure 2)

Project's MECR less than 1 per million

A project which results in a maximum increase in potential cancer risk of less than 1 per million, after the T-BACT requirements are met, would be approvable.* To identify the maximum increase in risk, the difference between the post-project potential cancer risk and the pre-project potential cancer risk needs to be evaluated at every receptor location. The CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, (January 1992) provides guidance on defining receptors and conducting dispersion modeling analysis.

Project's MECR greater than or equal to 1 per million and less than 100 per million

A project which results in a maximum increase in a potential cancer risk of greater than or equal to 1 per million but less than 100 per million, after permit unit T-BACT requirements are met, would be required to conduct an entire source risk evaluation. (See subsection C). The final permit decision would be based on the entire source risk evaluation.

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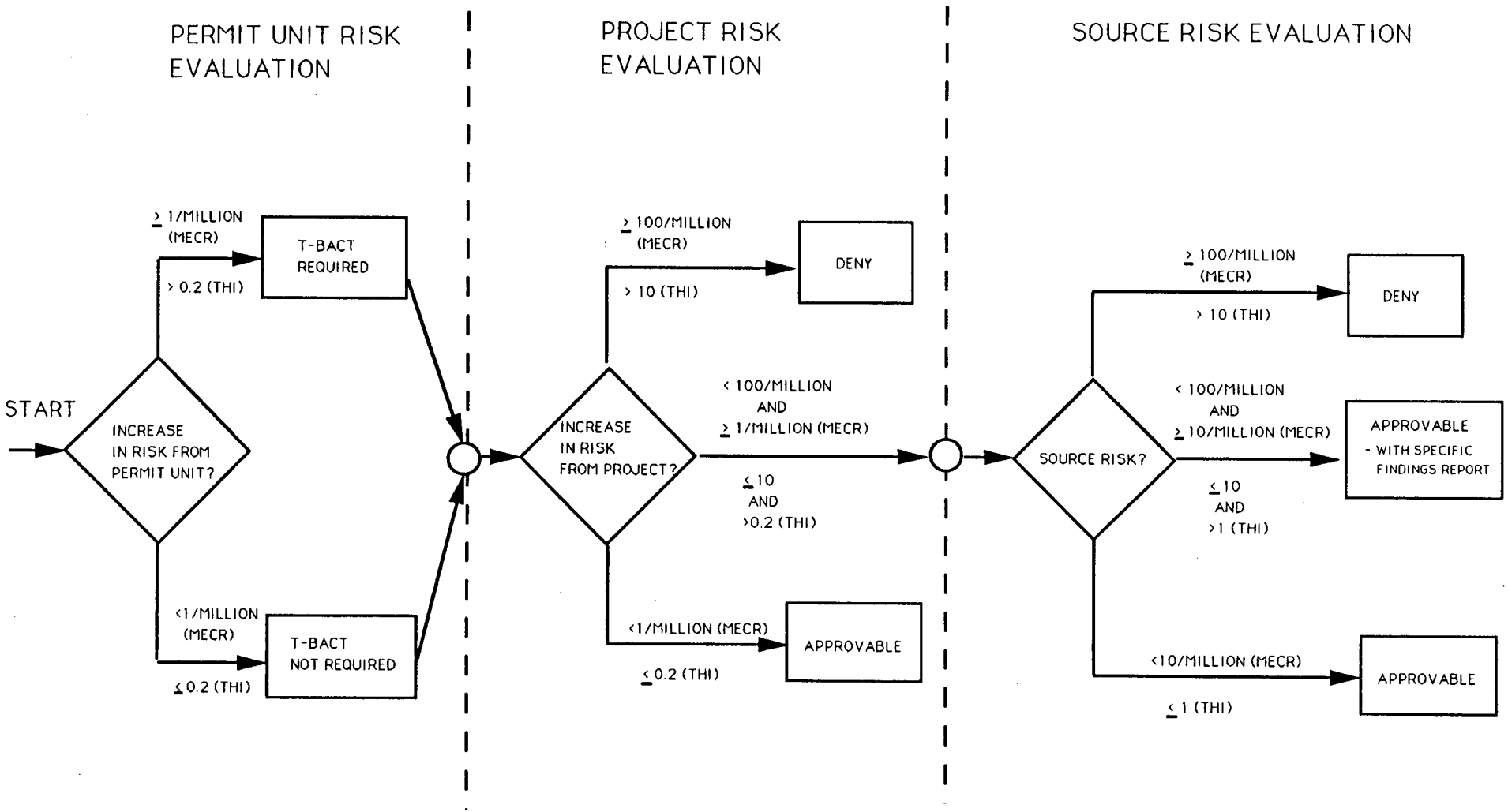
* Assuming source meets the potential cancer risk requirements, all other district requirements, any applicable state toxic control measures, and any federal MACT requirements.

Figure 2: Overview of the Modified Source Cancer and Noncancer Risk Evaluation Process



NOTE: CANCER RISK AND NONCANCER RISK ARE EVALUATED SEPARATELY.

MECR = MAXIMUM EXCESS CANCER RISK

THI = TOTAL HAZARD INDEX

Project's MECR greater than or equal to 100 per million

A project which results in a maximum increase in a potential cancer risk greater than or equal to 100 per million, after permit unit T-BACT requirements are met, would be denied a permit.

C. Entire Modified Source Risk Evaluation (Figure 2)

Modified source's MECR less than 10 per million

A modified source with a potential MECR (post-project) of less than 10 per million, after permit unit T-BACT requirements are met, would be approvable by the district.

Note: In determining the risk for the entire source, we suggest that the district use permitted emissions for all permit units if those permit units have enforceable permit conditions and the permit unit has been included in a previous district permitting action. As an option, the districts could consider the use of actual emissions for those permit units that are not part of the project if the modified source has prepared a risk assessment pursuant to the requirements of AB 2588.

Modified source's MECR greater than or equal to 10 per million and less than 100 per million

A modified source with a potential MECR estimate greater than or equal to 10 per million and less than 100 per million, after permit unit T-BACT requirements are met, is approvable provided the applicant submits a Specific Findings Report and the APCO finds that a permit should be issued.

Modified source's MECR greater than or equal to 100 per million

A modified source with a potential MECR estimate greater than or equal to 100 per million, after permit unit T-BACT requirements are met, would be denied a permit.

STEP 2: EVALUATION OF NONCANCER RISK - MODIFIED SOURCE

A. Permit Unit T-BACT Analysis (See Figure 2)

T-BACT would be required on each permit unit whose emissions result in an increase in the total hazard index greater than 0.2.

Note: We suggest that the districts use the maximum permitted emissions to determine the difference between the post-project risk and pre-project risk from each modified permit unit. The use of actual emissions to determine the pre-project risk may be more appropriate in situations where the pre-project emissions have not been established by enforceable permit conditions and where the permitted emissions have not been used to assess risk in a

previous district permitting action. In this case, we suggest that the districts use the actual average annual emissions.

B. Project Risk Evaluation (Figure 2)

Project's total hazard index value less than or equal to 0.2

A project which results in a maximum increase in the total hazard index value of less than or equal to 0.2 at any receptor location, after permit unit T-BACT requirements are met, would be approvable.* To identify the maximum increase in the total hazard index value at a receptor location, the difference between the post-project total hazard index values and the pre-project total hazard index values needs to be evaluated.

Project's total hazard index value greater than 0.2 and less than or equal to 10

A project which results in a maximum increase in the total hazard index value of greater than 0.2 but less than or equal to 10 at any receptor location, after permit unit T-BACT requirements are met, would be required to conduct an entire source risk evaluation. Approval or denial of the project would be based on the entire source risk evaluation.

Project's total hazard index value greater than 10

A project that results in a maximum increase in the total hazard index value of greater than 10, after permit unit T-BACT requirements are met, would be denied a permit.

C. Entire Modified Source Risk Evaluation

Modified source's total hazard index value less than or equal to 1

A modified source with a total hazard index value less than or equal to 1, after T-BACT requirements are met, would be approvable by the district.

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* Assuming source meets the potential noncancer risk requirements, all other district requirements, any applicable state toxic control measures, and any federal MACT requirements.

Note: In determining the risk for the entire source, we suggest that the district use permitted emissions for those permit units that are not part of the project if those permit units have enforceable permit conditions and the permit unit has been included in a previous district permitting action. As an option, the districts could consider the use of actual emissions for those permit units that are not part of the project if the modified source has prepared a risk assessment pursuant to the requirements of AB 2588.

Modified source's total hazard index value greater than 1 and less than or equal to 10

A modified source with a total hazard index value estimate greater than 1 but less than or equal to 10, after T-BACT requirements are met, is approvable provided the applicant submits a Specific Findings Report and the APCO finds that a permit should be issued.

Modified source's total hazard index value greater than 10

A modified source with a total hazard index value estimate greater than 10, after permit unit T-BACT requirements are met, would be denied a permit.

EXAMPLE CASE

A source is modified by adding permit units A and B, and removing permit unit C from service. The project to be permitted is comprised of permit units A, B, and C.

Risk information:

Permit Unit	Cancer Risk	Noncancer Risk
A	20 per million	0
B	30 per million	2
C	10 per million	0

Evaluation:

Permit Unit T-BACT Analysis: T-BACT for cancer risk is required on permit units A and B. T-BACT for noncancer risk is required on permit unit B.

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* Assuming source meets the potential cancer risk requirements, all other district requirements, any applicable state toxic control measures, and any federal MACT requirements.

Risk information after T-BACT installed:

Permit Unit	Cancer risk	Noncancer risk
A	10 per million	0
B	15 per million	1
C	10 per million	0

Project Risk Evaluation: Project results in an increase in cancer risk of 15 per million (A+B-C), and an increase in noncancer risk of 1. An entire modified source risk evaluation is required for both cancer and noncancer risk.

Modified Source (post-project) risk information:

MECR	Noncancer risk
30 per million	3

Entire Modified Source Risk Evaluation: The project would be approvable provided the applicant submits a Specific Findings Report for both cancer and noncancer risk and the APCO concludes the permit should be approved.

H. Additional Provisions

Independent of these guidelines, new and modified sources would also be subject to the following:

1. Sources are subject to the requirements of any emission standard and/or any MACT promulgated by the U.S.EPA. The time limits allowed by the district should be consistent with those required by U.S.EPA's requirements.

2. Sources are subject to the requirements of any airborne toxic control measure adopted by ARB pursuant to AB 1807 (Toxic Air Contaminant Identification and Control).

3. Sources are subject to the requirements of any rules or regulations adopted by a district to limit toxic emissions.

4. Sources which increase risk and are located within 1,000 feet of a school are required to notify:

   i) parents of children in any school within one-quarter mile of the source, and

   ii) each address within a 1,000 foot radius of the source's property line. (Health & Safety Code Section 42301.6)

I. Offsets

The issue of allowing offsite offsets has been raised numerous times during the development of these guidelines. In theory, the idea of allowing emission reductions achieved at one source to be used at another is quite reasonable. However, in practice, an offsite offset program for toxic pollutants would be resource intensive, difficult to administer and present significant compliance problems. Therefore, we have not suggested such a program as part of these guidelines.

J. Specific Findings

We suggest submitting a Specific Findings Report to the APCO if the MECR for a new or modified source is greater than or equal to 10 per million or the total hazard index value is greater than 1, or both. The Specific Findings Report provides the APCO with information upon which he or she can decide on whether the permit should be granted.

We believe it is important for the APCO to identify and make available to the public the written findings which support the decision to permit or not permit a source. The APCO may also wish to conduct a public meeting to receive comment from interested parties. Listed below are definitions of key terms and examples of the type of information that may be included in the report.

1. Key terms

Feasible Reduction Measures

Feasible reduction measures are control measures and techniques that are technologically feasible and economically practicable and include, but are not limited to, changes of basic control equipment, product substitution or modification, process modifications, feedstock modifications, operational and maintenance improvements, and enclosing systems or processes to reduce emissions. Feasible reduction measures are different from T-BACT in that they apply to existing permit units. They are similar to T-BACT in that feasibility is determined on a case-by-case basis.

Beyond T-BACT

Beyond T-BACT is any combination of control measures that are needed to reduce a source's potential risk below an applicable criterion value. Beyond T-BACT may include more effective control measures than the

measures listed in the definition of T-BACT as well as enforceable limitations on the potential to emit.

2. **Content**

a. Identify pollutant(s) that would be emitted.

The report should identify the toxic air pollutants that would be emitted from the source. It should briefly discuss any adverse health effects that are associated with these substances.

b. Identify the health impact of the toxic pollutant(s) that would be emitted.

The cancer and noncancer risk associated with the toxics that would be emitted from the new or modified source should be identified and discussed. The applicant may also wish to discuss potential cancer burden as a measure of communicating the magnitude of the potential cancer risk. As specified in the CAPCOA Air Toxics "Hot Spots" Program Risk Assessment Guidelines, (January 1992) the permit applicant should also discuss how currently undeveloped areas are "zoned" (i.e. commercial or residential) and use this information to estimate potential health impacts should this area be developed. The applicant may wish to present information on the likelihood that an individual could reside at the point of maximum offsite cancer risk.

c. Discuss the uncertainty in the risk assessment process.

The permit applicant may wish to include information regarding uncertainty in the risk assessment process as described in the chemical health effects documents.

d. Discuss the benefits associated with the new or modified source.

The permit applicant may wish to include information regarding the benefit the new or modified source would provide the local community. Benefits of the source may include the service provided to the community or a decrease in risk compared to risk estimates without the source.

e. Identify federal, state, or local mandates.

The permit applicant may indicate whether there are any existing federal, state, or local mandates that require him/her to modify an existing source or establish a new source. For example, the state's clean fuel regulations may require an existing gasoline station to offer clean fuel for sale. In order to comply, the owner of the gasoline station may have to modify the facility to add a clean fuel pump.

f. Identify multi-media impacts.

The APCO should require the permit applicant to identify the impact the new or modified source may have on media other than air.

g. Discuss the findings of the California Environmental Quality Act (CEQA) document if one was required for the project.

Independent of these guidelines, the APCO must review environmental impact reports (EIRs) that are prepared by the Lead Agency pursuant to the requirements of the CEQA. This document should provide information regarding background, cumulative, and ecological risk. Background risk is the risk associated with the ambient toxic air pollutant emissions level due to local stationary sources and mobile sources. Cumulative risk is the sum of the risk of toxic air pollutant emissions from local stationary sources within a given area. Ecological risk is the risk to flora and fauna resulting from emissions of toxic air pollutants.

h. Identify sensitive receptors impacted by the new or modified source.

The APCO may require the permit applicant to identify any sensitive receptor locations impacted by the toxic air emissions from the new or modified source. A sensitive receptor location includes, but is not limited to, any hospital, school, or day-care center.

i. Provide a risk reduction plan.

The APCO may require or the permit applicant may wish to provide a risk reduction plan identifying all feasible reduction measures to reduce potential risk from the source.

The risk reduction plan should:

i. Identify which processes and activities cause toxic emissions and what portion of the total potential source risk is due to each.

ii. Identify all feasible reduction measures and applicable beyond T-BACT measures for the source type.

iii. Estimate the risk reduction potential of the feasible reduction measures and beyond T-BACT measures.

iv. Estimate how long it would take to implement the feasible reduction measures and beyond T-BACT measures.

v. Determine the technical feasibility and cost-effectiveness of the feasible reduction measures and beyond T-BACT measures for the individual source.

vi. Identify the feasible reduction measures and beyond T-BACT measures that will be implemented to reduce potential risk and a detailed schedule for implementation. If the plan shows that these measures are insufficient to meet the lower risk level, the plan should identify possible reductions in the future.

APPENDIX 1

Current Work in the Risk Assessment/Risk Management Area

1. Guidelines for Carcinogen Identification and Risk Assessment

The Office of Environmental Health Hazard Assessment (OEHHA) is in the process of developing guidelines for carcinogen identification and risk assessment. The OEHHA has published an overview which outlines the issues to be addressed in their revised Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale. The revised guidelines will update both hazard identification and dose-response assessment. Exposure assessment will be the subject of a separate document pursuant to Senate Bill (SB) 1731 (Risk Reduction Audits and Plans).

Specific areas which will be addressed by the OEHHA in the revised guidelines include: 1) the use of genotoxicity data in assessing hazard and dose-response, 2) the use of data on mechanisms of carcinogenesis to improve the reliability of dose-response assessment, and 3) the use of mechanistic models as a tool for hypothesis. Also, standard procedures to be used in deriving cancer potency from animal experiments when data for pharmacokinetic corrections and mechanistic approaches are not adequate will be developed. Guidance regarding the use of data from epidemiological studies in dose-response assessment will be expanded. Guidance will be provided on the use of pharmacokinetic data in dose-response and cancer potency evaluations. Procedures to formally treat uncertainties in hazard identification and dose-response evaluations will be added to the guidelines. The treatment of human heterogeneity issues will be broadened.

In developing these guidelines, the OEHHA will consider the information presented in the National Academy of Sciences (NAS) study to review health risks from air pollutants, the United States Environmental Protection Agency's (U.S.EPA) exposure assessment guidelines, and the State of California's Comparative Risk Project. The following subsections describe these studies and reports in further detail.

The OEHHA anticipates that in 1994 they will complete the revisions to these cancer guidelines.

2. National Academy of Sciences (NAS) Study to Review Health Risks from Air Pollutants

The NAS is currently reviewing U.S.EPA's risk assessment methodology in accordance with provisions contained in the 1990 Federal Clean Air Act Amendments. The NAS report will review techniques used by U.S.EPA to assess not only the risk of cancer from exposure to air pollutants, but also the risk of other health effects such as birth defects and reproductive dysfunctions. The report will be available to assist agencies in responding to the residual risk requirements of the Federal Clean Air Act (FCAA).

The issues that the study will address include uncertainty in risk assessment, emission and exposure characterization, threshold vs. non-threshold toxicity, extrapolation from high-dose animal test to low-dose human exposure, complex mixtures of pollutants, and interactions among pollutants.

The FCAA requires the report to be submitted to U.S.EPA in May 1993.

3. U.S.EPA Guidelines for Exposure Assessment-May 29, 1992

U.S.EPA issued in May 1992 guidelines establishing a broad framework for exposure assessments. These guidelines describe the general concepts of exposure assessment and include definitions. These guidelines provide guidance on planning and conducting an exposure assessment as well as provide guidance on presenting results of exposure assessments and characterizing uncertainties.

These guidelines standardize terminology used in exposure assessments done for the U.S.EPA. They emphasize that exposure assessments done as part of a risk assessment need to consider the hazard identification and dose-response parts of the risk assessment in the planning stages of the exposure assessment so that these two parts can be smoothly integrated into risk characterization. The guidelines discuss a number of approaches and tools for exposure assessment such as point-of-contact, scenario evaluation, and reconstruction of dose. The guidelines stress the importance of fully presenting exposure estimates along with supporting information in risk assessment documents. The U.S.EPA suggests that the risk assessor should also identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions and limitations, as well as the scientific basis and rationale for each assessment.

4. The Comparative Risk Project Workplan

The California Environmental Protection Agency (Cal/EPA) has begun a comparative risk project. The Comparative Risk Project provides the blueprint to target California's environmental investment toward those activities, processes, and substances which pose the greatest risk to public health and the environment. The purpose of the project is to identify and prioritize the most important environmental risks facing California's citizens and ecosystems. At the same time, methods to mitigate the identified risks will be evaluated and recommended.

The Comparative Risk Project is scheduled to conclude by January 1994.

APPENDIX 2

Air Toxics Risk Management Programs in California

1. District Requirements

a. South Coast

The South Coast Air Quality Management District (SCAQMD) adopted Rule 1401 for new, modified, and relocated sources which emit carcinogens. The rule limits the cumulative impact of cancer risk near the source to 1 per million without toxic best available control technology (T-BACT) or 10 per million with T-BACT. The cumulative impact is the impact of all permit units installed on or after June 1, 1990 and located within 100 meters of the new, modified or relocated unit. The risk for a single year must not exceed one-70th of these risk values. In addition, the potential cancer burden is also limited to 0.5 excess lifetime cancers.

The SCAQMD allows for several exemptions from its basic permitting rule. These exemptions include: 1) change of ownership, 2) a modification or relocation with a risk reduction, or 3) no increase in risk. The SCAQMD allows replacement of functionally identical equipment and onsite offsets--provided that risk decreases and T-BACT is installed on new equipment. Publicly owned treatment works (POTWs) and remediation efforts are exempt from meeting risk limits provided that T-BACT is installed. Finally, there is a delayed compliance provision which allows a 100 per million cumulative risk impact if the applicant can demonstrate that strategies beyond T-BACT will result in risk levels below 10 per million within five years. Noncancer effects of toxic air pollutants are not addressed in the rule.

The SCAQMD is currently revising Rule 1401 and is in the process of developing proposed Rule 1402 that will address existing sources of toxic emissions.

b. Monterey Bay

The Monterey Bay Unified Air Pollution Control District (MBUAPCD) adopted Rule 1000 for new and modified stationary sources. This rule requires noncarcinogenic emissions to have "reasonable control technology" in place, and carcinogenic emissions to have "best control technology" in place. The cancer risk is based on "the human individual assumed to be at the point of maximum ground level impact on an annual basis" and is limited to 10 per million. In addition, the cancer and noncancer one hour emissions impact from toxic emissions are limited to one-420th of the permissible exposure level (PEL). This rule exempts dry cleaners and gasoline dispensing sources.

c. Bay Area

The Bay Area Air Quality Management District (BAAQMD) has a Board-adopted policy for new and modified sources. T-BACT is required for certain

source categories and projects emitting potentially toxic substances in amounts exceeding a cancer risk level of one per million. The cancer risk may not exceed 10 per million. The established threshold level for noncarcinogenic compounds may not be exceeded. The BAAQMD has exempted gasoline dispensing sources using Phase I and Phase II vapor recovery and dry cleaners using closed-looped, dry-to-dry machines with a total solvent use of less than 100 gallons/year. The BAAQMD is working on a proposed toxic new source rule for new and modified sources of toxic emissions.

2. State Requirements

a. AB 1807

The Air Resources Board's (ARB) air toxic control program, established under Assembly Bill (AB) 1807 (Toxic Air Contaminant Identification and Control), is designed to reduce public exposure to those toxic air pollutants presenting the greatest potential risk to public health. It is a two-phase process that separates risk assessment from risk management. The emission reductions required by AB 1807 are based upon what is technologically feasible, with consideration given to the level of risk that would remain after control and the cost of the control technology.

Under AB 1807, the air toxic control measures (ATCMs) regulate emissions from stationary sources. Examples of source categories addressed by these measures include chrome plating operations and gasoline stations. The districts are required to adopt regulations no less stringent than the ATCMs developed by the ARB. The AB 1807 process promotes uniformity and consistency among various district regulations.

b. AB 2588

AB 2588, the Air Toxics "Hot Spots" Information and Assessments Act of 1987, established a statewide program for the inventory of toxic air emissions from individual sources as well as requirements for risk assessments and public notification of potential health risk. Owners of certain stationary sources are required to report the type and quantity of certain toxic air pollutants routinely released from their sources. The districts are required to prioritize sources as high, intermediate, or low based on the reported emissions. All sources designated as high priority are required to prepare and submit a health risk assessment to the district. The health risk assessment must be reviewed by the OEHHA and approved by the district. If the district determines significant health risks are associated with emissions from the source, the source operator must notify all exposed individuals of the results of the risk assessment.

AB 2588 complements the AB 1807 process by locating sources of substances not currently under evaluation. AB 2588 also provides exposure information for establishing priorities for regulatory action.

The AB 2588 Toxics Committee, which includes representatives from 11 districts and staff of the ARB and the OEHHA, has published risk assessment and public notification guidelines. The purpose of the risk assessment guidelines is to provide risk assessment procedures for use in the

preparation of health risk assessments required by AB 2588. The purpose of the public notification guidelines is to provide districts with a tool for developing notification procedures.

c. SB 1731

SB 1731 (Risk Reduction Audits and Plans) amends the "Hot Spots" program by requiring districts to review and oversee the implementation of risk reduction plans developed by existing high priority sources of toxic air pollutants. These sources are identified through the health risk assessments submitted to the districts in compliance with the requirements of AB 2588 (Air Toxics "Hot Spots" Information and Assessment Act of 1987). Allowing each source to develop its own risk reduction plan affords sources of toxic air pollutants some flexibility in choosing which risk-reduction measures to implement. ARB will assist smaller businesses in complying with the risk reduction audit and plan requirements by developing self-conducted audits and checklists. Implementation of SB 1731 (Risk Reduction Audits and Plans) should result in the expeditious control and reduction of risk from a wide variety of sources.

d. AB 2728

In 1992, AB 2728 (Coordination with the Federal Act) was signed into law. This bill is designed to integrate federal air toxic emission standards with the AB 1807 program. Specifically, the bill required the ARB designate the 189 federal hazardous air pollutants listed in Section 112 (b) of the FCAA as toxic air contaminants, and this was done in April 1993. In addition, the bill specifies that any promulgated federal emission standard will become an ATCM, unless the ARB takes specific action to modify the federal emission standard.

3. Federal Requirements

The 1990 amendments to the FCAA address toxic air emissions. Because the Risk Management Guidelines are intended for the control of toxic emissions, the following information will focus on the air toxics provisions of the FCAA, Section 112. The toxic air pollutants provisions of the FCAA have restructured existing law so that U.S.EPA will be able to regulate area source and industrial categories rather than concentrating on individual pollutants. The specifics of the federal requirements are in various states of completion, and are not fully defined. However, it is our intention that the Risk Management Guidelines be consistent with the federal requirements. In the following paragraphs, we have identified several major provisions of the FCAA that may impact risk management decisions in California.

a. 189 HAPs

Congress established a list of 189 hazardous air pollutants (HAPs) which U.S.EPA must regulate from major sources and area sources. The FCAA defines major toxic sources as emitting greater than 10 tons/year of any individual HAP or greater than 25 tons/year of any combination of HAPs. Area sources, defined as any source which is not major, must also have

standards set for them. U.S.EPA published a list of major and area source categories which emit these HAPs on July 16, 1992 (57 Federal Register 31576). These source categories are to be regulated within ten years. Sources will be required to install the maximum available control technology (MACT). Further emission reductions will be required later if there remains a significant residual risk after installation of MACT. The addition of 189 HAPs significantly expands the number of regulated toxic compounds.

b. MACT Standards

MACT for newly constructed or reconstructed sources (i.e. new source MACT) is defined as the level of hazardous air pollutant emission control that is no less stringent than the emission limitation achieved by the best performing similar source. MACT for existing and modified sources (i.e. existing source MACT) is defined as the average emission limitation achieved by the best performing 12 percent of existing sources for sources with 30 or more sources in the category or subcategory. This existing source MACT determination excludes sources which, within specified time periods, comply with the lowest achievable emission rate applicable to the source category and prevailing at the time, whether or not the source is subject to that standard. MACT for sources with less than 30 sources in the category or subcategory is the average emission limitation achieved by the best performing 5 existing sources. When no federal MACT standard has been promulgated, the FCAA requires the Administrator to determine a MACT emission limitation on a case-by-case basis. Sources in California must comply with federal MACT standards, or in the case where no standard has been promulgated, a case-by-case MACT determination is required.

c. Modifications

In draft regulations, U.S.EPA has proposed to define a modification as a physical change or a change in the method of operation of a major source which results in a greater than de minimis actual or potential increase in HAPs emissions. Emissions, greater than a de minimis amount (discussed in subsection e.), from modifications to any major source under the FCAA must be controlled to a level no less stringent than MACT for existing sources. Decisions in California for control technology on modifications may be affected depending on the de minimis level selected for the federal requirements.

d. Offsets

Under a draft U.S.EPA proposal to implement Section 112(g) of the FCAA, a modification would not be subject to existing source MACT standards if the HAP increase is offset. The Administrator must approve a showing by the owner or operator that the increase in the emissions of any HAP emitted in greater than de minimis amounts from the modification will be offset by an equal or greater decrease in the emissions of another HAP(s) from a more hazardous source. U.S.EPA has not yet clarified the approach required to implement this provision or whether states will have to implement this provision.

e. De Minimis

EPA is proposing that actual emissions increases must exceed "de minimis amounts" to be considered a modification. De minimis amounts may be as large as 10 tons/year for some pollutants. De minimis levels for some HAPs may be set by state and/or local agencies in accordance with the delegation guidelines for the FCAA. Emissions from modifications to major sources which are less than or equal to de minimis amounts may not be subject to existing source MACT unless the state and/or local agency receives delegation to be more stringent.

We agree with the concept of de minimis for preventing activities that would yield no benefits or only trivial benefits from exhausting scarce administrative resources. However, the de minimis levels in these Risk Management Guidelines might need to be changed depending on final delegation of the federal requirements to the state.

f. Delegation

Section 112(l) of the FCAA allows state and local air pollution control authorities to voluntarily seek partial or complete delegation to implement and enforce emission standards and other requirements of the federal toxics program. Under the FCAA, U.S.EPA is required to prepare guidance that would be useful to the states in developing programs. Current U.S.EPA staff thinking is for a state and local program approval process, followed by delegation of individual emission standards or program elements. The specifics of the delegation process are not yet proposed. The benefit of obtaining approval or delegation is to avoid dual and potentially conflicting requirements for industry.

g. Permits

U.S.EPA will require permits for all major pollution sources. The purpose of requiring permits is to allow U.S.EPA to directly enforce permit requirements by consolidating all requirements into a Title V operating permit.

Each state must submit its state permit program to U.S.EPA by November 15, 1993. U.S.EPA must approve or disapprove all of the state programs within 12 months. The state has 180 days to amend its program if disapproved by U.S.EPA. Sources subject to the permit program must submit a complete permit application to the state within 12 months of the effective date that U.S.EPA approved the relevant state program. The state must issue the first round of permits for existing major sources within three years after U.S.EPA approval of the state permitting authority.

APPENDIX 3

Components of a Health Risk Assessment

A health risk assessment (HRA) is an evaluation of the potential for adverse health effects that can result from exposure to emissions of toxic air pollutants. Cancer potency values and noncancer acceptable exposure levels (AELs) for toxic air pollutants are used in the HRA process. This information can be used by risk managers when assessing and managing the risk from individual sources. The HRA process may be divided into four components: 1) hazard identification; 2) exposure assessment; 3) dose-response assessment; and 4) risk characterizations. The following text describes these four components in more detail.

Hazard Identification

Hazard identification is the process of determining the potential adverse health effects (cancer, birth defect, etc.) associated with emitted toxic air pollutants. It involves characterizing the nature and strength of the evidence of causation. Although the question of whether a substance causes cancer or other adverse health effect is theoretically a yes-no question, there are relatively few chemicals on which the human data are definitive. Therefore, the question is often restated in terms of effects in laboratory animals or other test systems, for example, "Does the agent induce cancer in test animals?" Positive answers to such questions are typically taken as evidence that an agent may pose a cancer risk for any exposed humans. Information from short-term laboratory tests and information from similarly structured known compounds may also be considered.

Dose-Response Assessment

A dose-response assessment is the process of characterizing the relationship between the exposure to a toxic air pollutant and the incidence or severity of an adverse health effect in exposed populations. It usually requires extrapolation from high to low dose and extrapolation from animals to humans.

The dose-response relationship is expressed in terms of a potency slope which is used to calculate the probability or risk of cancer associated with a given exposure level. For noncarcinogenic effects, dose-response data developed from animal or human studies are used to develop noncancer AELs (acute and chronic).

Exposure Assessment

Exposure assessment involves determining: 1) the concentrations of the various pollutants in media by which humans are exposed; 2) the contact rates via inhalation, ingestion and dermal exposure; and 3) exposure duration.*

Long-term average daily dose can be calculated from the estimated concentrations in the various media. Short-term exposure via inhalation is calculated based on estimated ambient air concentrations. These calculations of dose are then used in the risk characterization for individuals. In addition, the nature and size of the potentially exposed population is evaluated as part of an exposure assessment.

Risk Characterization

As the final step of health risk assessment, risk characterization is an integration of the health effects and public exposure information developed for the toxic air pollutant. The results of this integration of information is the quantification of the cancer and noncancer risk associated with the toxic air pollutant. When quantifying cancer risk, the risk assessor recommends a cancer potency value or range of values that best represents the risk resulting from exposure to one unit volume or mass of the toxic air pollutant. When quantifying noncancer risk, the risk assessor recommends AELs (acute and chronic) of the toxic air pollutant. These cancer potency values and AELs are just two of the many factors considered by risk managers when determining the appropriate level of control for a new or modified source of toxic air contaminants. These factors are combined with exposure data to determine risk.

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* Air emissions contaminate not only the air, but deposit onto water, soil, vegetation, and may end up in the food chain. These media represent the many pathways of exposure to toxic air pollutants.

APPENDIX 4

Description of Weight of Evidence and Probabilistic Modeling

The following material is informational in nature and does not reflect the views of the Air Resources Board (ARB) or the Office of Environmental Health Hazard Assessment (OEHHA).

1. Weight of Evidence

There are varying degrees of confidence in the strength of the evidence that a pollutant is, in fact, a human carcinogen. Some believe that the cancer potency factor and estimates of individual cancer risk should be accompanied by a weight of evidence indicator. Weight of evidence is an approach used to indicate the extent to which the available biomedical data support the hypothesis that a substance causes an effect in humans. For example, the following factors increase the weight of evidence that a chemical poses a hazard to humans: an increase in the number of tissue sites affected by the agent; an increase in the number of animal species affected, an increase in the number of experiments and doses showing a response; and the occurrence of a clear-cut dose-response relationship. In addition, a high level of statistical significance in the occurrence of the adverse effect in treated subjects compared with untreated controls increases the weight of evidence. Also, a dose related shortening of the time of occurrence of the adverse effect increases the weight of evidence.

The United States Environmental Protection Agency (U.S.EPA) uses a system that characterizes the overall weight of evidence based on the availability of animal, human, and other supportive data. This system is an attempt to establish the likelihood that an agent is a human carcinogen and thus influences the confidence in the estimation of potential health risks. The U.S.EPA classification contains five categories:

Group A	Known Human Carcinogen
Group B	Probable Human Carcinogen
Group C	Possible Human Carcinogen
Group D	Not Classified
Group E	No Evidence of Carcinogenicity in Testing

Category A is the strongest classification and is based upon human data from the work place and other sources. It also may be supported by animal test results. Category B is based upon convincing animal test data but inadequate evidence in humans. Two subcategories of Group B are frequently used, depending upon the strength of the animal evidence. Category C is based upon limited animal evidence and inadequate supporting human evidence; this is the weakest of the carcinogen classifications. Categories D and E are provided to classify those substances for which there is insufficient data to make a determination (Group D) or to classify substances that have been tested and found not to cause cancer in experimental animals (Group E).

2. Probabilistic Modeling

Human population exposure assessment is an essential element of risk assessment. The nature and extent of exposure, along with the toxicity estimate of the substances involved, determines the degree of risk. Current exposure assessment methodology requires the use of several fixed parameters including a 70-year lifetime exposure.

Probabilistic approaches utilize statistical distributions in place of fixed parameters. Supporters of probabilistic approaches argue that the use of probabilistic modeling incorporates a greater degree of realism in air toxics exposure assessment than standard assessment methodology.

Computer models are available which allow probability distribution to be input and which perform Monte Carlo statistical analysis on input equations. The computer programs provide comprehensive reports on the statistical distribution of the output variables.

One particular model combined population residency and mortality data with information on daily activity patterns to calculate a lifetime average daily exposure distribution. Each Monte Carlo iteration simulated a separate exposed individual, with the model estimating the fraction of life exposed for the individual by generating a life exposure history. The age and sex of each individual was chosen from population distributions determined using 1980 census data. Exposure was defined to occur during the individual's tenure at their current residence, ceasing upon change of residence or death. Mobility was characterized using census data on the probability of moving during the previous 5 years. Mortality was characterized using actuarial tables. The number of hours exposed depended on daily activity pattern. Except for ages under 18 and over 65, where activity patterns were uniquely determined by age, patterns were assigned randomly, with individuals assumed to change pattern every 7 years.